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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,972	05/11/2001	Barry Ross	017227/0171	7954

7590 07/15/2003

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	20

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/786,972	Applicant(s) ROSS, BARRY	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and request for continued examination under 37 C.F.R. 1.114 filed 05/02/03. Claims 1-12 and 15 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/02/03 has been entered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84. Copy of Form PTO 948, Notice of Draftsperson's Patent Drawing Review is attached.

Claim Rejections - 35 USC § 112

3. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (WO 95/34595).

Matthews teaches a compound and a composition comprising said compound. The compound is a polyamidoamine or polylysine dendrimer that has a plurality of terminal cationic or anionic containing moiety (abstract, pages 2-6 and claims 1-40 and figure 1). The composition is administered orally, rectally, topically, transdermally, parenterally and nasally to a patient in need thereof to treat infections caused by toxins. An example of such an infection is HIV. See page 7, line 6 to page 9 line 14 and claims 37-40. The teachings anticipate the claims.

Applicant appears to draw a distinction between antiviral activity and inhibition of toxic material or substance by stating that antiviral activity refers to the inhibition of the replication of the virus and not to the replication of any toxic material/substance originating from the virus. Applicants further state that toxin is not an infectious agent like a virus.

Upon reference to applicant's specification, page 9, lines 4-10, and figure 1 it appears that "toxic materials or substances" embrace the actual viruses themselves as well as toxic substances released from the viruses. New claim 15 recites virus as a biological organism. Therefore, when interpreting the claims in view of applicant's specification, the Examiner respectfully submits that the claims even as amended appear to read on method of inhibiting viral activity.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-12 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36, 38 and 39 of U.S. Patent No. 6,190,650. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claims because the examined claim is either anticipated by or would have been obvious over the reference claims. See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In this case, claim 38 of the reference prophylactically or therapeutically treats viral infection in human or non-human with the composition of claim 1. Claim 1 of the reference encompasses claim 7 of the application. The application for the most part recites a method of inhibiting toxic material where the toxic material is a viral infection (claims 1 and 12) and the method comprises administering an effective amount of a dendrimer to a patient in need thereof. The issued patent for the most part teaches a dendrimer composition and a method for administering the composition to treat the same conditions or infections that are caused by toxins. Treating or treatment encompasses inhibiting. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of the issued patent. One having ordinary skill in the art would have been motivated to administer the composition of the issued patent to a patient in need thereof with the expectation that the composition would treat or inhibit activity of the toxic material or substance released from viral infection.

Applicant agues that the issued patent is not directed to inhibiting the activity of a toxic substance and not a method for antiviral treatment.

Upon reference to applicant's specification, page 9, lines 4-10, and figure 1 it appears that "toxic materials or substances" embrace the actual viruses themselves as well as toxic substances released from the viruses. Instant claim 12 recites that viral infection can produce toxins and instant claim 15 recites a virus as a biological organism. Therefore, when interpreting the claims in view of applicant's specification, the Examiner respectfully submits that the claims even as amended appear to read on method of inhibiting viral activity. The scope of the issued patent is encompassed within the scope of the claimed invention.

A terminal disclaimer will overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
July 11, 2003